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10/551,456	09/30/2005	Nitin Bhalachandra Dharmadhikari	053180	3014

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WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

EXAMINER	
WELTER, RACHAEL E	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
12/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentmail@whda.com

Office Action Summary	Application No.	Applicant(s)	
	10/551,456	DHARMADHIKARI ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/16/09 has been entered.

Claim Status

Claims 1 and 3-24 are pending. Claims 24 is newly added. Claim 2 is cancelled.

Withdrawn Rejections

The rejection of claims 1, 3-11, 16-19, 21, and 22 rejected under 35 U.S.C. 102(b) as being anticipated by Balaban et al (US Patent No. 5,209,746) is withdrawn in light of applicant's amendments.

Claim Rejections - 35 USC § 112

Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19-22 recite the limitation "...wherein the cover composition forms at least one of a plug or a band blocking the passageway." There is insufficient antecedent basis for this limitation in the claim since the claims are dependent on claim 1, which does not explicitly recite a "cover composition."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (US Patent No. 6,004,582) as evidenced by Amidon et al (US Patent No. 5,229,131).

Faour et al teach a multi-layered osmotic device that allows for the immediate delivery of a first active agent followed by a monitored, continuous, controlled, and/or retarded delivery of a second active agent which is the same or different as the first

active agent (column 1, lines 7-10). The osmotic device comprises a compressed core comprising a first active agent, an osmotic agent, and optionally PVP, a semi-permeable membrane surrounding the core and having a preformed passageway therein (the membrane is permeable to a fluid in the environment of use and substantially impermeable to the first active agent), and an inert water soluble polymer coat comprising poly (vinylpyrrolidone)-(vinyl acetate) copolymer partially or substantially completely surrounding the semi-permeable membrane and plugging the passageway in the wall (column 3, lines 49-65). The device also comprises an external coat comprising a second active agent for immediate release of the drug (column 3, lines 65-67). The active agent may be susceptible to decreased stability in the gastric environment, such as niacin, targeted to the intestine for local action, such as beclomethasone, or an agent which has a side effect of causing bleeding or irritation of the gastric mucosa, such as aspirin or naproxen (column 14, lines 29-30, 36; column 15, line 43).

Although Faour et al suggest the use of a water soluble polymer coat partially surrounding the semipermeable membrane that plugs the passageway; Faour does not explicitly teach a coating to substantially cover only the passageway.

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to look at the guidance provided by Faour et al and substantially cover only the passageway. One would have been motivated to do so to alter the release pattern of the dosage form, which is dependent on the needs of a particular patient population. A coating substantially only covering the passageway would result

in a more immediate release of the core drug. Furthermore, the examiner notes that since "substantially" in the instant specification, the limitation of claim 1 allows for some coating to be applied elsewhere other than the passageway.

Regarding claims 10 and 17, which are directed to a dosage form exhibiting a pulsatile release, Faour's invention can have multiple separate drug layers, with multiple membranes and can release the beneficial agents in a concurrent manner. Thus, it is an expected property that Faour's system produces a pulsatile release (Figure 2; column 5, lines 58-64).

Regarding claims 12-15, Faour et al teach that the compositions may be designed to achieve pH-dependent and pH-independent delivery of the active agent (column 5, lines 58-61). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to create pH-dependent or pH-independent drug delivery systems with a reasonable expectation of success. One would have been motivated to do so since Faour et al suggest the creation of pH-dependent or pH-independent embodiments of the drug delivery system. Regarding the limitations of the targeted drug delivery being dependent on or independent of gastric emptying, Amidon et al disclose that pH dependent release systems affect release based on the variable pH in the small intestine and affect release time through gastric emptying; thus pH-dependent and pH-independent embodiments of Faour's invention would exhibit delays either dependent on or independent from gastric emptying time, respectively (column 5, lines 18-35 and 56-65; column 10, lines 62-68) as evidenced by Amidon et al.

Regarding claim 21, the examiner notes that applicant has not defined a band or distinguished a band from a plug in the instant specification. Additionally, the examiner notes that like the plug, the band is comprised of an erodible polymer composition. As such, it is the position of the examiner that the water-soluble polymer coating of Faour et al would reasonably read on both a plug and a band blocking the passageway.

Response to Arguments

Applicant's arguments filed 9/16/09 have been fully considered but they are not persuasive.

Applicant argues that Faour insists on the dual role of the polymeric suspension "which blocks the passageway and forms the polymer coat." Applicant argues that a substantial portion of the semipermeable membrane in Faour needs to be covered to ensure that the core will not imbibe quickly after the external coat has dissolved. As such, applicant argues that a person of ordinary skill in the art would be taught away from reducing the coverage of the coat to substantially cover only the passageway. Applicant further notes that all the examples of Faour use a complete covering of the semipermeable membrane by the coat. Moreover, applicant argues that Faour does not provide any significant guidance regarding how to reduce a complete coat cover to provide a partial coat cover, except as to a general statement. Applicant submits that a person skilled in the art might think of infinite possibilities for a partial coating according to Faour. Applicant argues that even if a person of ordinary skill in the art would have attempted to explore the possibility of reducing the full coverage area of the

semipermeable membrane that a person would expect undue difficulties in view of Faour because Faour insists on the requirement that at least a portion of the semipermeable membrane must be covered as well as the passageway.

In response to applicant's arguments, the examiner first notes that instant claim 1 recites, "...a composition applied so as to substantially cover only the passageway..." Because the claim recites "substantially" and the term is not defined in the specification for ascertaining its requisite degree, the instant limitation allows for some coating to be applied elsewhere other than the passageway. As such, it is noted that the features upon which applicant relies (i.e., a composition covering only the passageway) are not recited in independent claim 1. Although claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Second, even though Faour does suggest that the composition blocks the passageway as well as forms a partial coating on the semipermeable membrane, it is the position of the examiner that it would be obvious to use the composition to only cover the passageway. One would have been motivated to do so to alter the release pattern of the dosage form, which is dependent on the needs of a particular patient population. As such, if an ordinary skilled artisan wanted a faster release, it would be obvious to use less coating and only coat the passageway. Even though applicant argues that Faour exemplifies only using a complete covering of the semipermeable membrane by the coat, the examiner directs applicant's attention to MPEP 2123. "Disclosed examples and preferred embodiments do not constitute a teaching away

from a broader disclosure or nonpreferred embodiments." *In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).* Applicant has not provided evidence that the drug delivery systems of Faour could not be formulated or incapable of working when using the coating composition to cover only the passageway and applicant's mere arguments do not constitute a persuasive teaching away. Furthermore, even though Faour does not provide explicit guidance on how to reduce a complete coat cover to provide a partial coat cover, it is the position of the examiner that this process is well known in the pharmaceutical art and one would be motivated to try different partial coatings, such as the possibilities on pg. 10 of applicant's arguments depending on the desired release rate. Even though an ordinary skilled artisan would just as easily coat the entire semipermeable membrane to obtain a more controlled release, it is the position of the examiner that it would be just as easy to use less coating, covering only the passageway to obtain a more immediate release.

Applicant further argues that in contrast to the prior art, the presently claimed invention uses the cover composition only to substantially cover the passageway in order to reduce physical contact or interaction with the polymer that can affect the stability of the active ingredient present in the core, while achieving a same effect of programmed delivery of the active agent. Applicant also notes that the amount of polymer material, the manufacturing time, and the manufacturing facility requirements can be significantly reduced when substantially only the passageway is to be covered as opposed to a partially surrounding or full coat as in Faour.

In response to applicant's argument that the present invention uses the cover composition to only substantially cover the passageway in order to reduce physical contact or interaction with the polymer that can affect the stability of the active ingredient present in the core, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Finally, with respect to claims 19-22, applicant argues that Faour fails to teach or suggest a cover composition forming at least one of a plug or band blocking the passageway and Amidon fails to remedy this deficiency.

In response to applicant's arguments that Faour does not explicitly teach a band, the examiner notes that applicant has not defined a band or distinguished a band from a plug in the instant specification. Additionally, the examiner notes that like the plug, the band is comprised of an erodible polymer composition. As such, it is the position of the examiner that the water-soluble polymer coating of Faour et al would reasonably read on both a plug and a band blocking the passageway.

Thus, applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

New Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens et al (US Patent No. 5,474,784) as evidenced by Amidon et al (US Patent No. 5,229,131).

Stevens et al teach a controlled release device that can be administered orally and comprises a water impermeable capsule having at least one orifice wherein said orifice is closed by the insertion of a plug which is soluble or dispersible in water (column 1, lines 19-24). The contents of the hollow body are to be released as a pulse in the human body (claim 1). In example 5 of Stevens et al, the soluble plugs were comprised of the water-soluble polymer, polyvinyl pyrrolidone (column 7, lines 4-7). The capsules are coated with an impermeable coating comprised of preferably polyvinyl chloride (column 5, lines 47-49). Additionally, the core comprises excipients including polyvinyl pyrrolidone, which as evidenced by the instant specification on pg.15, line 13 can be an excipient that swells when exposed to an aqueous environment. Furthermore, the active agent may be susceptible to decreased stability in the gastric environment, such as anti-ulcer agents, targeted to the intestine for local action, such as 5-amino salicylic acids, or an agent which has a side effect of causing bleeding or

irritation of the gastric mucosa, such as piroxicam and diclofenac (column 14, lines 10-11, 24, & 29).

Regarding claims 12-15, Stevens et al teach that its compositions are designed to achieve pH-dependent and pH-independent delivery of the active agent by optionally incorporating pH-sensitive materials (column 2, lines 50-53). Regarding the limitations of the targeted drug delivery being dependent on or independent of gastric emptying, Amidon et al disclose that pH dependent release systems affect release based on the variable pH in the small intestine and affect release time through gastric emptying; thus pH-dependent and pH-independent embodiments of Stevens' invention would exhibit delays either dependent on or independent from gastric emptying time, respectively (column 5, lines 18-35 and 56-65; column 10, lines 62-68) as evidenced by Amidon et al. Furthermore, regarding instant claims 6-11 and 16-18, which are directed to the release of the drug delivery system, it is the position of the examiner that since Stevens et al teach a composition with same components, the composition of Stevens would obviously exhibit the instant release as well as be capable of exhibiting the instant release. According to MPEP 2112.02, products of similar chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches a similar chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)*. Thus, burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980)*. The claimed properties would have been

present once the composition was employed in its intended use as *In re Best, 195 USPQ 433*.

Regarding claim 21, the examiner notes that applicant has not defined a band or distinguished a band from a plug in the instant specification. Additionally, the examiner notes that like the plug, the band is comprised of an erodible polymer composition. As such, it is the position of the examiner that the water-soluble polymer coating of Stevens et al would reasonably read on both a plug and a band blocking the passageway.

Conclusion

Claims 1 and 3-24 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
December 6, 2009